

Remarks

Claims 8-11 are pending in the present application.

Consistent with the requirements of 37 CFR 1.133, "Interviews", Applicants request that the Examiner make of record the telephonic interview of 17 April 2004 wherein the Examiner offered to allow Claims 8-11 if Applicants agreed to Terminal Disclaimer specifically to disclaim the term of a patent issuing from the present application extending beyond the expiration of the full term of US Patent No. 5,939,550. In addition, the Examiner is requested to make of record that the Applicants declined to agree to the Examiner's offer.

Presently, Claims 8-11 are rejected as under 35 USC 101 for double patenting, under 35 USC 103(a), and for obviousness-type double patenting.

The Examiner's rejections of pending Claims 8-11 shall now be addressed in the order made by the Examiner.

Rejection of Claims 8-11 Under 35 USC 103(a)

The Examiner has rejected pending Claims 8-11 under 35 USC 103(a) as being obvious over WO 97/07800 (hereinafter "Allen et al.") in view of EP 093297 (hereinafter Chiu et al.).

Contrary to the Examiner's statement, Chiu et al. is not a valid reference. Rather, Chiu et al. is the European counterpart application of the present Application. Both Chiu et al. and the present Application claim the benefit of US Provisional Application 60/071,601 which was filed on January 16, 1998.

Further, even if Chiu et al. was not the European counterpart application of the present application, it would still not be a valid reference against the present Application as its publication date was July 21, 1999 and

the priority date of the present Application is January 16, 1998.

Therefore, the invention of Claims 8-11 as being obvious over Allen *et al.* in view of Chiu *et al.* is not proper as Chiu *et al.* is not a valid reference.

Rejection of Claim 10 Under the Judicially Created  
Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected Claim 10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of US Patent No. 6,066,647.

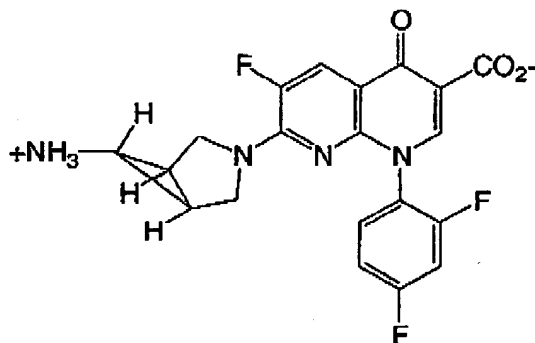
The Examiner states that US 6,066,647 teaches a method of forming a protonated form of the instant compound of formula VII via amine deprotection of the compound of formula II of US 6,066,647.

The Examiner further stated that the difference between the prior art process and the instantly claimed process is that the prior art process taught forming a protonated form of the instant compound of formula VIII by using an amine deprotection agent while the present Application claims the hydrolysis of the instant compound of formula VI with methanesulfonic acid to form the compound of formula VII.

Furthermore, the Examiner stated that Kiso *et al.*, Chem. Pharm. Communications, pages 5024-5027 (1988), teaches that methanesulfonic acid is a deprotecting agent for N-protected moieties.

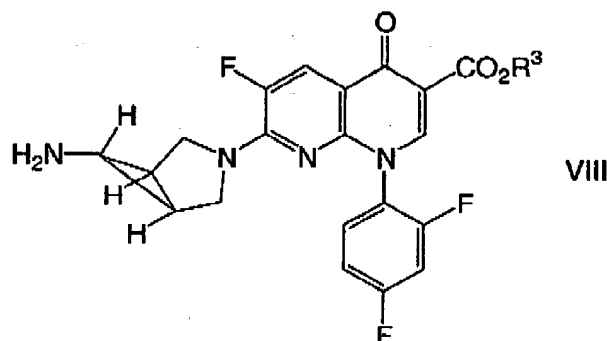
Claim 3 of US 6,066,647 teaches a process for forming a compound having the structure

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The compound formed by the method of claim 3 of US 6,066,647 is a free acid.

Applicants' process, as recited in Claim 10, forms a compound having the following structure:



R<sup>3</sup> is C<sub>1</sub>-C<sub>6</sub> alkyl. The compound formed by the Applicants' process is not a free acid but is an ester.

Therefore, contrary to the Examiner's statement, the compounds formed by the prior art process and the Applicants' process are not the same compounds

Furthermore, in the Applicants' process, a compound of formula VIII is formed by hydrolyzing a compound of formula VI with methanesulfonic acid and R<sup>3</sup>OH. Neither US 6,066,647 nor Kiso *et al.* either disclose or suggest forming the ester compound of formula VIII by reacting it with R<sup>3</sup>OH in combination with methanesulfonic acid.

Therefore, Claim 10 is not obvious, under the judicially created doctrine of obviousness-type double patenting, over claim 3 of US 6,066,647.

Rejection of Claim 11 Under the Judicially Created  
Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected Claim 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of US Patent No. 6,194,424.

The Examiner states that US 6,194,424 teaches that alatrofloxacin mesylate is a prodrug of trovafloxacin, which is the compound of formula VII of the present application.

Contrary to the Examiner's statement, US 6,194,424 does not have a claim 8 as it only has six claims. Further, US 6,194,424 does disclose or discuss alatrofloxacin mesylate or trovafloxacin. Rather, US 6,194,424 only relates to arylacetamides. Alatrofloxacin mesylate and trovafloxacin are not arylacetamides.

Therefore, Claim 11 is not obvious, under the judicially created doctrine of obviousness-type double patenting, over US 6,194,424.

Rejection of Claim 11 Under the Judicially Created  
Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected Claim 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 5,164,402.

The Examiner states that US 5,164,402 teaches N-protected trovafloxacin compounds which are obvious over the Applicants' acyl protected compounds. The Examiner also states that the difference between the compounds of US 5,164,402 and the compounds of Claim 11 is that the prior art only teaches amino protection whereas in the Applicants' compounds, both the amino and carboxyl

moieties are protected. The Examiner concludes that it would have been obvious to synthesize a prodrug wherein both moieties are protected.

Contrary to the Examiner's statement, the compounds of Claim 11 are not obvious in view of the compounds disclosed in claim 1 of US 5,164,402. In the compounds of Claim 11, the amino group is protected by the acyl group  $R^2C(O)-$ . Rather, in the compounds of claim 1 of US 5,164,402, the amino substituents are all non-acyl groups.

Further, claim 1 of US 5,164,402 specifically teaches prodrugs of the compound of claim 1 having free amino groups. US 5,164,402 neither discloses nor suggests compounds of its formula I wherein the amino group is protected by an acyl group and wherein the carboxyl group is protected by an alkyl group.

Therefore, Claim 11 is not obvious, under the judicially created doctrine of obviousness-type double patenting, over US 5,164,402.

Rejection of Claims 8-11 Under 35 USC 103(a)

The Examiner has rejected Claims 8-11 as being obvious over US Patent No. 5,164,402 in view of Bundgaard (Reference D, page 33).

The Examiner did not provide any Reference D (see attached Notice Of References Cited).

Further, the Examiner did provide a Bundgaard Reference W. However, only pages 27-30 were provided. This reference does not have a page 33.

Therefore, Applicants' cannot respond to the present rejection as the basis of this rejection, in view of what specific art is being cited, is not clear.

Rejection of Claim 8 Under 35 USC 101

The Examiner has rejected Claim 8 under 35 USC 101, for statutory double patenting, as claiming the same invention as that of claim 8 of co pending US Application No. 1998-71601P. This same rejection was made twice in the Office Action of April 26, 2004 on page 8 and again on page 10.

Contrary to the Examiner's statement, US Application No. 1998-71601P is not a co pending application. Rather, US Application No. 1998-71601P is a provisional application that was filed on January 16, 1998. Further, the present Application claims the benefit view of US Application No. 1998-71601P (60/071,601).

Therefore, the Examiner's rejection is improper.

Rejection of Claim 9 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected Claim 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of co pending US Application No. 1998-71601P.

Contrary to the Examiner's statement, US Application No. 1998-71601P is not a co pending application. Rather, US Application No. 1998-71601P is a provisional application that was filed on January 16, 1998. Further, the present Application claims the benefit view of US Application No. 1998-71601P (60/071,601).

Therefore, the Examiner's rejection is improper.

Rejection of Claim 10 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has rejected Claim 10 under the judicially created doctrine of obviousness-type double

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patenting as being unpatentable over claim 10 of co pending US Application No. 1998-71601P.

Contrary to the Examiner's statement, US Application No. 1998-71601P is not a co pending application. Rather, US Application No. 1998-71601P is a provisional application that was filed on January 16, 1998. Further, the present Application claims the benefit view of US Application No. 1998-71601P (60/071,601).

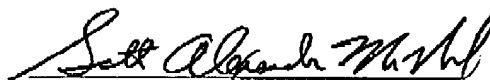
Therefore, the Examiner's rejection is improper.

Conclusion

In view of the above, Applicants respectfully submit that all of the Examiner's rejections of the pending claims, under 35 USC 101, under 35 USC 103(a), and under the judicially created doctrine of obviousness-type double patenting, are not proper. Therefore, Applicants respectfully request that these rejections of Claims 8-11 be withdrawn. Applicants further request that a notice of allowance be issued for pending Claims 8-11.

Respectfully Submitted:

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